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10/549,284

09/16/2005

Toru Sano

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EXAMINER

HURST, JONATHAN M

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,284	<b>Applicant(s)</b> SANO ET AL.
	<b>Examiner</b> JONATHAN M. HURST	<b>Art Unit</b> 4153

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/16/2005</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 09/16/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the five foreign documents, indicated as A1 - A5, and crossed out on PTO-1449, have not been considered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1-3 and 6-8 rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al. (US 5,304,487)

Regarding claim 1 Wilding et al. discloses a microchip comprising a base material in which a channel is provided (See Fig. 1, C 5 L 7-14, and Abstract where flow channel 20 is provided in substrate 14), the microchip extracting a sample from a complex of said sample and a carrier holding said sample being introduced into said channel (See Abstract where lysis occurs on a sample complex and cellular material contained in complex is extracted ), wherein said channel includes: an inlet through which said complex is introduced (See Fig. 1 and C 5 L 7-14 where there is an inlet port 16);

a damming portion which stems said complex; (See Fig. 1, Fig. 5, and C 7 L 38-68 where posts 26 located in region 22 extending from a flow channel are a damming portion)

an introduction channel which is provided from said inlet to said damming portion, said complex flowing through said introduction channel; (See Fig. 1 where 20A is an introduction channel from entry 16A to damming portion 22)

and a sample channel which is located on a downstream side of said damming portion, (See Fig. 1 and C 7 L 38-68 where channel 20B is located downstream of channel damming portion 22)

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said sample channel being communicated with said introduction channel through said damming portion, (See Fig. 1 and C 7 L 38-68 where damming portion is located between and in communication with both channel 20A and 20B)

said sample flowing through said sample channel, said sample being extracted from said complex stemmed at said damming portion. (See Fig. 1 and C 6 L 40-62 where lysis extracting occurs in region 22 at a damming portion)

Regarding claim 2 Wilding et al. discloses all the claim limitations as set forth above as well as the microchip, comprising a stimulus applying unit applying stimulus to said complex to extract said sample, said complex being stemmed at said damming portion. (See Fig. 1, and C 6 L 40-62 where stimulus applied at said damming portion 22 is a piercing stimulus caused by stimulus applying protrusions 24)

Regarding claim 3 Wilding et al. discloses all the claim limitations as set forth above as well as the microchip wherein said damming portion has a plurality of protrusions. (See Fig. 5 and C 7 L 39-67 where damming portion has protrusions 26)

Regarding claim 6 Wilding et al. discloses all the claim limitations as set forth above as well as the microchip, wherein said channel has a separation portion which separates a component in said sample. (See Fig. 1, C 9 L 20-27 where region 40 sample is fractionated and particular components are separated by binding)

Regarding claim 7 Wilding et al. discloses all the claim limitations as set forth above as well as the microchip wherein said channel has an analysis portion which analyzes said sample. (See Fig. 1, C 9 L 20-27, and C 10 L 1-13 where in region 40 detection analysis is performed)

Regarding claim 8 Wilding et al. discloses all the claim limitations as set forth above as well as the microchip wherein, wherein said channel has a recovery portion which recovers said sample. (See Fig. 1 exit portion 16B)

4. Claims 9-10, 13, 17, 20, 24, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Culbertson et al. (US 6,783,647)..

Regarding claim 9 Culbertson et al discloses a method of extracting a sample (See C 3 L 1-8 where intracellular content sample is released),  
wherein a microchip comprising a base material in which a channel is provided (See C 3 L 1-8 where microchannel is provided in a substrate)  
  
is used to introduce a complex of a sample and a carrier holding said sample into said channel  
(See C 9 L 62- C10 L 28 and Fig. 5 where complex flows through channel 164)

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and said sample is extracted from said complex by applying stimulus to said complex. (See C 3 L 7-12 where electric field stimulus applied to sample extracts sample from a cell by causing cell lysis)

Regarding claim 10 Culbertson et al. discloses a method of separating a sample, wherein, after said sample is extracted from the complex by the method of extracting a sample, a component in said sample extracted is separated on a downstream side of said channel. (See C 6 L 40-50 where downstream of cell lysis extraction the sample is separated)

Regarding claim 13 Culbertson et al. discloses all the claim limitations as set forth above as well as the method of separating a sample, wherein said stimulus is applied to said complex by diluting a concentration of said carrier. (See C 2 L 30-37 where lysis is performed by addition of a chemical and it is inherent that the concentration of the carrier in the channel will be diluted by said chemical)

Regarding claim 17 Culbertson et al. discloses a method of analyzing a sample, wherein after said sample is extracted from the complex by the method of extracting a sample, said sample extracted is analyzed on a downstream side of said channel. (See C 6 L 40-50 and C 12 L 3-9 where downstream of cell lysis extraction the sample is analyzed)

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Regarding claim 20 Culbertson et al. discloses all the claim limitations as set forth above as well as the method of analyzing a sample, wherein said stimulus is applied to said complex by diluting a concentration of said carrier. (See C 2 L 30-37 where lysis is performed by addition of a chemical and it is inherent that the concentration of the carrier in the channel will be diluted by said chemical)

Regarding claim 24 Culbertson et al. discloses method of recovering a sample, wherein after said sample is extracted from the complex by the method of extracting a sample, said sample extracted is recovered on a downstream side of said channel. (See C 6 L 40-50 ,C 11 L 11-24, and C 12 L 3-9 where cellular material sample is extracted from a cell when lysis occurs and sample is further separated and analyzed)

Regarding claim 27 Culbertson et al. discloses all the claim limitations as set forth above as well as the method of recovering a sample, wherein said stimulus is applied to said complex by diluting a concentration of said carrier. (See C 2 L 30-37 where lysis is performed by addition of a chemical and it is inherent that the concentration of the carrier in the channel will be diluted by said chemical)

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (US 5,304,487) as applied to claims 1-3 and 6-8 above, and further in view of Cheng et al. (US 6,403,367)

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Regarding claim 4 Wilding et al. discloses all the claim limitations as set forth above but does not disclose the microchip, wherein said stimulus applying unit is a heating member.

Cheng et al. discloses a microchip for analysis of a sample (See Abstract and C 1 L 41-55) including a stimulus applying unit applying stimulus to said complex to extract said sample complex wherein said stimulus applying unit is a heating member. (See C 5 L 60-67 and C 6 L 19-27 where lysis extracts a sample from a cell complex and stimulus causing lysis can be created using a heating element)

Cheng et al. and Wilding et al. are analogous because both references teach the use of cell lysis in microfluidic/microchip systems for analysis of a sample

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the heating member stimulus applying unit of Cheng et al. to the microchip of Wilding et al. because doing so provides an effective cell lysis means as required by Wilding et al. (See Wilding C 7 L 39-50 and Cheng C 6 L 19-27)

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (US 5,304,487) as applied to claims 1-3 and 6-8, above, and further in view of Culbertson et al. (US 6,783,647).

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Regarding claim 5 Wilding et al. discloses all the claim limitations as set forth above but does not disclose the microchip wherein said stimulus applying unit is a light irradiation member. (See C 2 L 51-62 where stimulus causing lysis can be created using laser light)

Culbertson et al. discloses a microfluidic system for analysis of a sample (See Abstract) including a stimulus applying unit applying stimulus to said complex to extract said sample complex and wherein said stimulus applying unit is a light irradiation member. (See C 1 L 10-16 and C 2 L 51-62 where lysis extracts a sample from a cell complex and stimulus causing lysis can be created using laser light)

Culbertson et al. and Wilding et al. are analogous because both references teach the use of cell lysis in microfluidic/microchip systems for analysis of a sample

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the light irradiation stimulus applying unit of Culbertson et al. to the microchip of Wilding et al. because doing so provides an effective cell lysis means as required by Wilding et al. (See Wilding C 7 L 39-50 and Culburtson C 2 L 51-62)

10. Claims 11-12, 18-19, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Culbertson et al. (US 6,783,647) as applied to claims 9-10, 13, 17, 20, 24, and 27 above, and further in view of Wick (US 7,250,138).

Regarding claims 11-12, 18-19, and 25-26 Culbertson et al. discloses all the claim limitations as set forth above including stimulus applied to a complex capable of causing cell lysis but does not disclose the method of separating a sample wherein said stimulus is applied to said complex by heating said complex or by changing pH in said channel. Culbertson also does not disclose the method of analyzing a sample wherein said stimulus is applied to said complex by heating said complex or by changing pH in said channel. Further Culbertson also does not disclose the method of recovering a sample wherein said stimulus is applied to said complex by heating said complex or by changing pH in said channel.

Wick et al. discloses a method of lysing a cell wherein a stimulus is provided and causes lysing. The said lysis causing stimulus can be changes in pH, temperature, and chemical means, among others. (See C 5 L 2-5)

Wick et al. and Culbertson et al. are analogous because both references disclose lysis performed on cells.

It would have been obvious to one of ordinary skill in the art at the time of invention to perform lysis by applying stimulus such as heat and pH in the methods of separating, analyzing, and recovering a sample because temperature and pH change fulfill the need for an effective cell lysis means as required by Wilding et al. (See Wilding C 7 L 39-50)

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11. Claims 14-16, 21-23, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Culbertson et al. (US 6,783,647) as applied to claims 9-10, 13, 17, 20, 24, and 27 above, and further in view of Liu (US 6,159,749).

Regarding claim 14-16, 21-23, and 28-30 Culbertson et al. discloses all the claim limitations as set forth above as well as wherein flow is stopped and started in a stimulus applying region (See C 4 L 16-21) but does not disclose the method of separating, analyzing or recovering a sample, wherein said stimulus is applied after said complex is stemmed at a predetermined position in said channel wherein said complex is stemmed by keeping said complex at said predetermined position by remote operation, wherein said remote operation is a laser trap.

Liu discloses a method of stemming a sample at a predetermined position by remote operation wherein said remote operation is a laser trap. (See C 1 L 10-30)

Liu and Culbertson et al. are analogous because both references teach analysis of chemical and biological moieties. (See Liu C 1 L 10-14 and Culbertson Abstract)

It would have been obvious to one of ordinary skill in the art at the time of invention to stem a sample at a predetermined position by remote operation wherein said remote operation is a laser trap as described by Liu in the methods of separating, analyzing, and recovering a sample of Culbertson et al. because doing so allows the sample to remain positioned in the cell lysis

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region for a sufficient amount of time and also allows starting and/or stopping of sample flow as described by Culbertson et al. (See Culbertson C 3 L 10-16 and C 4 L 15-21)

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on (571)272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./

Examiner, Art Unit 4153

/Basia Ridley/

Supervisory Patent Examiner, Art Unit 4153